

## REMARKS/ARGUMENTS

### **Specification**

A table (Table 1) and paragraph have been added following paragraph [0010] and amendments have been made to several paragraphs to re-number the tables for inclusion of an additional table.

No New Matter has been added by this amendment. Table 1 and the paragraph summarize information that is commonly known to people working in Chemistry, Biochemistry, and Nutrition.. Additionally, the new Table 1 and paragraph are material contained in the following research papers that were incorporated by reference in the original Specification.

The molecular weights of the tocotrienol and tocopherol isomers can be calculated from the chemical structures of the molecules in "Yu, C. C., M. Simmons-Menchaca, A. Gapor, B. G. Sanders, and K. Kline, 1999, Induction of apoptosis in human breast cancer cells by tocopherols and tocotrienols, *Nutr. Cancer* 33:26-32." Page 27, Figure 1A, shows tocopherol as the top structure and tocotrienol as the structure below it. The table below the structures shows the possible methyl substitutions for isomers of tocopherol and tocotrienol (Exhibit 1).

The molecular weights of alpha-tocotrienol and gamma-tocotrienol are given in "Cahoon, E.B., S.E. Hall, K.G. Ripp, T.S. Ganzke, W.D. Hitz, and S.J. Coughlan, 2003, Metabolic redesign of vitamin E biosynthesis in plants for tocotrienol production and increased antioxidant content, *Nat Biotech* 21(9):1082-1087" (Exhibit 1).

Page 1085, left column, Figure 5A shows the structure of alpha-tocotrienol and its MW of 424.

Page 1085, left column, Figure 5B shows the structure of gamma-tocotrienol and its MW of 410.

The molecular weights of alpha-, gamma-, and delta-tocotrienol are given in "Pearce, B. C., R. A. Parker, M. E. Deason, A. A. Qureshi, and J. J. Wright, 1992, Hypocholesterolemic activity of synthetic and natural tocotrienols. *J Med Chem* 35:3595-606."

Page 3602, right column, paragraph 4, lines 1 and 5 shows the molecular weight of alpha-tocotrienol as 424 Daltons.

Page 3602, right column, paragraph 5, lines 1 and 5 shows the molecular weight MW of gamma-tocotrienol as 410 Daltons.

Page 3602, right column, paragraph 6, lines 1 and 5 shows the molecular weight MW of delta-tocotrienol as 396 Daltons.

Page 3596, left column, chart I (top figure) contains a figure of the structure of tocotrienol, with an additional table that explains possible methylation for the different isomers. The molecular weights of the tocotrienols can be calculated from this figure.

## Claims

### 35 USC 112, First Paragraph

#### Claims 48-50

Claims 48-50 have been rejected under 35 USC 112, First Paragraph as failing to comply with the written description. Specifically, the claims contain  $\leq$  and  $\geq$  symbols where the specification only contains  $<$  and  $>$  symbols.

Claims 48, 49, and 50 have been amended to remove the “equal to” from the “less than” and “greater than” symbols. These amended claims are supported by the specification at paragraph [0053]. The Examiner is requested to remove this rejection and allow the claims.

### 35 USC 112, Second Paragraph

#### Claims 39, 47, and 49

Claims 39, 47, and 49 have been rejected under 35 USC 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner has found the phrase “natural extract” to be indefinite. The Applicant stated in the Response to the Non-Final Rejection of the

originally filed application that the phrase “natural extract” was to be understood as defined by the FDA

The definition is repeated below:

*The term “natural extract” = Nonsynthetic (natural): A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act. [(21) Synthetic: The term “synthetic” means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.]*

The Examiner is requested to remove this rejection and allow the claims.

35 USC 102(b)

Claims 1, 37 and 38

Claims 1, 37 and 38 have been rejected under 35 USC 102(b) as being anticipated by Tan et al. (US 6,350,453). The Examiner has stated that Tan et al. teaches that the byproduct oil from *Bixa orellana* contains delta- and gamma-tocotrienols and it meets the limitations of Claim 1.

Claim 1 has been amended to read “selected from the group consisting of between 1:25 to 8:1 and between 10:1 to 25:1” and Claim 37 has been amended to read “between 10:1 to 8:1 .

It is not sufficient that Tan et al. discloses the presence of delta- and gamma-tocotrienols in the byproduct oil, but that the reference discloses the ratios of delta- to gamma-tocotrienols in the claims. Tan et al. only discloses the 9:1 ratio of delta- to gamma-tocotrienols found in nature (Exhibit 2 – Tan Declaration). This ratio has been excluded from Claim 1. Claims 1, 37 and 38 claim delta- to gamma-tocotrienols ratios to be found in manufactured products, which offer improved benefits over the natural byproduct oil.

In light of the amendments, the Examiner is requested to remove this rejection and allow the claims.

35 USC 102(b)

Claims 47-50

Claims 47-50 have been rejected under 35 USC 102(b) as being anticipated by Tan et al. (US 6,350,453). The Examiner has specifically pointed out that Tan et al. teaches an annatto byproduct oil and a natural extract when a vegetable oil is added to the distillation of the tocotrienols.

Independent Claims 47 and 49 have been amended to add the limitation of “the 350 - 450 Dalton MW fraction of a natural extract”. This range of molecular weights includes the various isomers of tocotrienol and tocopherol, while excluding the molecular weights of the vegetable oils used for cooking (generally in the range of 800-900 Daltons) (Exhibit 2 – Tan Declaration).

The experiment in Tan et al. cited by the Examiner used Palm oil (low end of MW is 807) to make the distillate more fluid rather than the viscous material without the oil (Exhibit 2 – Tan Declaration). The Palm oil did not add anything to the resulting distilled product as its molecular weight was too heavy. Therefore, the addition of Palm oil in the experiment does not disclose the inclusion of “the 350 - 450 Dalton MW fraction of a natural extract”.

In light of the amendments, the Examiner is requested to remove this rejection and allow the claims.

35 USC 103(a)

Claims 1, 25, and 37-50

Claims 1, 25, and 37-50 are rejected under 35 USC 103(a) as being obvious over Tan et al. (US 6,350,453) in view of Wright (US 5,217,992) in view of Meijer et al. (US 6,787,151). The Examiner has cited Tan et al. as disclosing the combination of an annatto extract and a natural extract producing tocotrienols 20-90% by weight; however Tan et al. does not disclose the amounts in the claims or that palm oil is specifically used together with the annatto extract.

Wright discloses that palm oil is a rich source of tocotrienols and are known to treat hypercholesterolemia, hyperlipidemia and thromboembolic disorders.

Meijer et al. discloses phytosterols, soy protein, niacin, chromium, soy lecithin, and chitosan improve cholesterol status.

Applicant has amended the claims as follows:

Claim 1 has been amended as discussed above.

Claim 25 has been amended to remove phytosterols, chitosan, soy protein, lecithin, chromium (all compounded forms), and niacin from the listed compounds. This amendment removes Meijer as Prior Art for this claim.

Independent Claims 47 and 49 have been amended, as discussed above, to add the limitation of “the 350 - 450 Dalton MW fraction of a natural extract”. This range of molecular weights includes the various isomers of tocotrienol and tocopherol, while excluding the molecular weights of the vegetable oils used for cooking (generally in the range of 800-900 Daltons).

Dependent Claim 42 has been amended to remove the phrase “vegetable oil” as it may be confused with cooking oils. Soy and corn have been added to the group of natural extracts. Paragraph [0017] discloses these products.

In light of the amendments to Claims 1, 25, 37, 39, and 42, the combination of Tan et al., Wright and Meijer et al. do not disclosed all the limitations of the claims and the Examiner is requested to remove this rejection and allow the claims.

#### New Claims

##### Claims 51 – 56

Independent Claim 51 claims a composition which is a mixture of “an oily byproduct extract of *Bixa orellana* seed and a 350 - 450 Dalton MW fraction of a natural extract” with a ratio of delta-tocotrienol to gamma-tocotrienol is between 1:25 to 25:1. Dependent Claims 52 – 53 claim delta-tocotrienol to gamma-tocotrienol ratios of 1:10 to 10:1 and 1:1. Dependent Claim 54 claims a natural extract selected from the group consisting of soy, corn, rice bran, palm, cranberry seed, and litchi seed. Support for these claims can be found in paragraphs [0042] and [0084].

Independent Claim 55 claims a composition which is a mixture of “an oily byproduct extract of *Bixa orellana* seed and a 350 - 450 Dalton MW fraction of a natural extract”. Dependent Claim 56 claims a natural extract selected from the group consisting of soy, corn, rice bran, palm, cranberry seed, and litchi seed. Support for these claims can be found in paragraphs [0017], [0052], [00120], and [00123].

## Conclusion

Claims 1, 25, 37-56 are currently pending. Claims 2-24 and 26-36 are Canceled. Claims 1, 25, 37, 39, 42, and 47-50 are amended. Claim 51-56 are New.

The claims have been amended to claim more precisely the disclosed invention. No new matter has been added by the amendments to the claims.

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefore, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested and it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Payment was made for 4 Independent Claims and less than 20 claims in total with the filing for an RCE. Payment is included with this filing for 2 additional Independent claims (6 Independent claims) and 2 additional claims above 20 total claims (22 total claims). No additional fees are believed due; however, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to credit card information.

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